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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,110	07/02/2003	David J. Zarbatany	BSI-410us1	3378
23122	7590	11/01/2005	EXAMINER	
RATNERPRESTIA P O BOX 980 VALLEY FORGE, PA 19482-0980			CHATTOPADHYAY, URMI	
		ART UNIT	PAPER NUMBER	
		3738		

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TWN

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/612,110	ZARBATANY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 July 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 36-39 and 82-98 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 36-39 and 91-98 is/are rejected.
- 7) Claim(s) 82-90 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 July 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/2/03
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. The Preliminary Amendment filed 7/2/03 has been entered. The changes to the specification and claims have been approved. Claims 1-35 and 40-81 have been canceled, and new claims 82-98 have been added. All pending claims 36-39 and 82-98 are being considered for further examination on the merits.

### ***Priority***

2. The first sentence of the specification regarding priority must be updated to indicate that application number 09/442,192 is now U.S. Patent No. 6,610,087.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) filed on 7/2/03 has been considered by the examiner. An initialed and signed copy of the PTO/SB/08A is enclosed.

### ***Specification***

4. The disclosure is objected to because of the following informalities:
  - a) On page 7, line 1 of the brief description of Fig. 2, it appears that "stent" should be changed to --stent-graft--.
  - b) On page 20, lines 2-3, it appears from Fig. 7 that " $d_4$  to  $d_3$  to  $d_2$  to  $d_1$ " should be changed to -- $d_2$  to  $d_3$  to  $d_4$  to  $d_1$ --.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 36-39, 91 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Lashinshi et al. (EP 0 796 597 A2, as cited in applicant's IDS).

Lashinshi et al. discloses a stent and process for making a stent with all the elements of claims 36, 91 and 96. See Figure 2, column 4, lines 24-26 and column 7, lines 2-8 for a stent (10) for holding open a body lumen, wherein the stent (10) comprises at least a first longitudinal region (12a, 12e) having first metallurgical properties and a second longitudinal region (12c) having second metallurgical properties different from the first metallurgical properties. See column 5, lines 3-8 for a process for making the stent (10) comprising the step of providing a different annealing history for the first longitudinal region (12a, 12e) as compared to the second longitudinal region (12c).

Claim 37, see column 5, lines 3-8 for the first metallurgical properties being caused by a first annealing history and the second metallurgical properties being caused by a second annealing history.

Claim 38, see Figure 2 and column 7, lines 2-8 for a transition region (12b, 12d) between the first longitudinal region (12a, 12e) and the second longitudinal region (12c) and having third metallurgical properties intermediate the first and second metallurgical properties.

Claim 39, see column 7, lines 2-10. In an embodiment with more than five sections, there will be more than one section in the transition region between first longitudinal region (end section 12a or 12e) and second longitudinal section (middle section 12c). Because the stent “gradually increases in degree of stenting...from either axial end toward the center”, the more than one section in the transition region will provide the transition region with a gradient of metallurgical properties between the first and second metallurgical properties.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 92-95, 97 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinshi et al. in view of Kleshinski et al. (USPN 5,746,765).

Lashinshi et al. discloses a stent and a process for making a stent with all the elements of claims 91 and 96, but is silent to the step of providing the different annealing history comprising exposing the first longitudinal region to a first thermal input which is greater than a second thermal input to which the second longitudinal region is exposed, as required by claims 92, 94 and 97. See column 5, lines 6-8 for the first longitudinal region (12a, 12e) being annealed more than the second longitudinal region (12c). Kleshinski et al. teaches a process for making a stent (32) wherein different sections of the stent are annealed at different temperatures, so that, like the Lashinshi et al. stent, the end cells (36) would not expand to provide full radial force on the

vessel (34) while the central section would. See column 8, lines 21-36. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Kleshinski et al. to have the first and second longitudinal regions of Lashinshi et al. annealed at different temperatures. Because the first longitudinal region (12a, 12e) is "annealed more" than the second longitudinal region (12c), it is obvious that the annealing temperature (thermal input) would be higher at this region than the annealing temperature (thermal input) at the second longitudinal region (12c). With respect to claims 94 and 98, see Figure 2 and column 7, lines 2-8 for a transition region (12b, 12d) between the first longitudinal region (12a, 12e) and the second longitudinal region (12c) and having third metallurgical properties intermediate the first and second metallurgical properties. With the use of different temperatures to anneal the various regions differently, it would have been obvious to have the transition region (12b, 12d) exposed to a third temperature intermediate the first and second temperatures.

Claim 93, see column 5, lines 6-8. Because the first longitudinal region (12a, 12e) is annealed more than the second longitudinal region (12c), the first longitudinal region (12a, 12e) is relatively less brittle and therefore, more flexible than second longitudinal region (12c).

Claim 95, see column 7, lines 2-10. In an embodiment with more than five sections, there will be more than one section in the transition region between first longitudinal region (end section 12a or 12e) and second longitudinal section (middle section 12c). Because the stent "gradually increases in degree of stenting...from either axial end toward the center", the more than one section in the transition region will provide the transition region with a gradient of metallurgical properties between the first and second metallurgical properties. In view of

Kleshinski et al., the gradient is achieved by exposing the transition region (12c) of Lashinshi et al. to a gradient temperature intermediate the first and second temperatures.

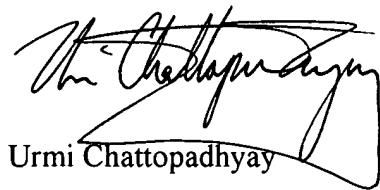
***Allowable Subject Matter***

9. Claims 82-90 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

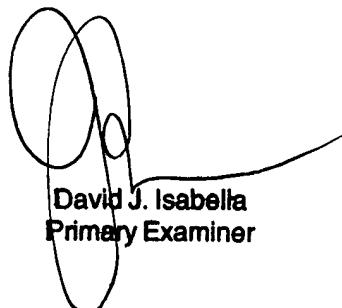
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmī Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmī Chattopadhyay  
Art Unit 3738



David J. Isabella  
Primary Examiner